

**REMARKS**

**A. Status of the Claims**

Claims 80, and 84-88 are pending. Claims 84 and 85 have been amended to correct typographical and grammatical errors. Therefore, no new matter is entered with this amendment.

**B. Antecedent Basis**

Claim 84 stands rejected as lacking antecedent basis for the term "said enzyme." Applicants have amended claim 84 to correct the error. Applicants thank the Examiner for pointing out this error.

**C. Definiteness**

Claims 80, and 84-88 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for the recitation of the phrase "a polypeptide consisting essentially of." Applicants respectfully disagree because:

- (1) The phrase "consisting essentially of" has a clear, unambiguous, and well-established meaning;
- (2) The phrase "polypeptide [or peptide] consisting essentially of" appears in at least 165 issued patents in the same context as in Applicants' claim 80; and
- (3) The meaning of Claim 80 would be immediately clear to one skilled in the art.

**1. The Meaning of "Consisting Essentially Of" Is Well-Established**

The phrase "consisting essentially of" is well-established in patent law. The Federal Circuit, the Court of Customs and Patent Appeals, various United States District Courts, the Board of Patent Appeals and Interferences, and the MPEP have all agreed that "[t]he transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention [quoting *In re Herz*, 537 F.2d 549 (CCPA 1976)(emphasis added)]." See MPEP §2111.03. The following list of opinions evidences the fact that "consisting essentially of" has a clear, unambiguous, and well-established meaning:

*In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1969);  
*PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998);  
*Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997);  
*Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 666, 7 USPQ2d 1097, 1102 (Fed. Cir. 1988);  
*Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 412 (Fed. Cir. 1984);  
*Norton Co. v. Carborundum Co.*, 530 F.2d 435, 189 USPQ 1 (1st Cir. 1976);  
*In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963);  
*BASF Corp. v. Eastman Chemical Co.*, 56 USPQ2d 1396, 1404-05 (D. Del. 1998);  
*Rogers Corp. v. Arlon, Inc.*, 855 F. Supp. 560, 568 (D. Conn. 1994);  
*General Electric Co. v. Hoechst Celanese Corp.*, 740 F. Supp. 305, 16 USPQ2d 1977 (D. Del. 1990);  
*Syntex (U.S.A.) Inc. v. Paragon Optical Inc.*, 7 USPQ2d 1001, 1016, 1037 (D. Ariz. 1987);  
*Dow Chemical Co. v. American Cyanamid Co.*, 615 F. Supp. 471, 484, 229 USPQ 171, 180 (E.D. La. 1985);  
*Air Products & Chem., Inc. v. Chas. S. Tanner Co.*, 219 USPQ 223 (D. S.C. 1983);  
*Medtronic, Inc. v. Catalyst Research Corp.*, 547 F. Supp. 401, 411-12, 216 USPQ 687, 696 (D. Minn. 1982);  
*Carter-Wallace, Inc. v. Gillete Co.*, 531 F. Supp. 840, 211 USPQ 499 (D. Mass. 1981);  
*Standard Oil Co. v. Montedison, S.p.A.*, 494 F. Supp. 370, 376 (D. Del. 1980),  
*Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Int'f 1989); and  
*Larkin v. Kauder*, 202 USPQ 193 (Bd. Pat. Int'f 1978).

In fact, Applicants are unaware of any decision by the Federal Circuit, the Court of Customs and Patent Appeals, a United States District Court, or the Board of Patent Appeals and Interferences, in which the phrase "consisting essentially of" has been ruled indefinite, *per se*.

**2. The Phrase "Polypeptide [or Peptide] Consisting Essentially Of" Appears in At Least 165 Issued Patents**

Applicants' representative, Kenneth E. Jenkins, performed a search on the USPTO electronic patent data base for issued claims including the phrase "peptide consisting essentially of" or "polypeptide consisting essentially of." The search resulted in some 165 issued patents. See Appendix A for complete listing of search results. Some exemplary claims include:

**U.S.P. 4,575,495**

1. A synthetic peptide consisting essentially of the following sequence of amino acids Arg Trp Met Met Leu Arg Arg (I) wherein said peptide is disposed on a carrier.

**U.S.P. 7,005,419**

8. A method for sensitizing a proliferating cell to a DNA base-damaging agent by inhibiting growth arrest and DNA damage-inducible gene 45 (GADD45) polypeptide activity comprising administering a polypeptide of [sic] consisting essentially of an amino acid sequence selected from a group of sequences from a wild type GADD45 (SEQ ID NO:2 having a DEDDDR (SEQ ID NO:5) subsequence having amino and carboxy ends, wherein the amino acids of the sequences are in their native order, are linear peptides, and further consist of the DEDDDR (SEQ ID NO:5) subsequence or of DEDDDR (SEQ ID NO:5) and of about 20 or fewer amino acids of SEQ ID NO:2 which naturally flank the DEDDDR (SEQ ID NO:5) subsequence at either or both the amino and carboxy ends, and are in their native order, and wherein said polypeptide inhibits GADD45 activity by at least 10%.

**U.S.P. 6,537,965**

1. An isolated biologically active peptide consisting essentially of the formula:

- (a) X<sub>01</sub>ValSerGluIleGlnLeuMetHisAsnLeuGlyLysHisLeuAsnSerMet  
GluArgValGluTrpLeuArgLysLysLeuGlnAspValHisAsnPhe (SEQ ID NO:  
1);
- (b) fragments thereof containing amino acids 1-29, 1-30, 1-31, 1-  
32, or 1-33;
- (c) pharmaceutically acceptable salts thereof; or
- (d) N-- or C-- derivatives thereof;  
wherein:  
X<sub>01</sub> is desamino Ser, desamino Ala or desamino Gly, provided  
that said peptide is not desamino-  
SerValSerGluIleGlnLeuMetHisAsnLeuGlyLysHisLeuAsnSerMetGluArgVa  
l GluTrpLeuArgLysLysLeuGlnAspValHisAsnPhe (SEQ ID NO:8) or a  
fragment thereof containing amino acids 1-31.

### U.S.P. 5,846,011

- 2. A substantially pure polypeptide consisting essentially of the  
amino acid sequence: leu tyr ser gly asn asp val thr asp ile  
ser asp asp arg phe pro lys pro pro glu ile ala asn gly tyr  
val glu lys leu phe arg tyr gin cys (SEQ ID NO: 1), wherein  
the polypeptide is specifically immunologically cross-reactive  
with polyclonal antibodies which specifically bind the gene  
product of the hpr gene.

### U.S.P. 5,227,466

- 6. An isolated fragment of the amino acid sequence of  
the human insulin receptor  $\alpha$  subunit, said  
fragment consisting essentially of an insulin  
binding site or an insulin-like growth factor I  
binding site.
- 7. A non-naturally occurring peptide consisting  
essentially of an amino acid residue sequence  
selected from the group consisting of ....

The fact that 165 issued patents include the use of the phrase "consisting essentially of" in the same context as Applicants' claim 80 is further evidence of the clear, unambiguous, and well-established meaning of this phrase.

### **3. The Definiteness Standard**

The provisions of 35 U.S.C. §112, second paragraph, merely require that the claims set forth subject matter with a *reasonable* degree clarity and particularity; absolute clarity is not required. See MPEP §2173.02. Indeed, as set forth in the MPEP:

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirement of clarity and precision, not whether more suitable language of modes of expression are available ... he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire." See MPEP §2173.02 (emphasis in original).

Thus, if the claims provide a reasonable degree of clarity, then the requirements of 35 U.S.C. §112, second paragraph are met, even where an examiner may feel alternative terms may possess a greater degree of clarity.

#### **4. Claim 80 is Clear and Definite**

In light of the rules and law set forth by the Federal Circuit, the Court of Customs and Patent Appeals, various United States District Courts, the Board of Patent Appeals and Interferences, and the MPEP, it would be clear to one skilled in the art that the phrase "polypeptide consisting essentially of" as set forth in pending Claim 80 means a single polypeptide whose composition includes:

- (a) a circularly permuted  $\beta$ -lactamase protein covalently bonded to
    - (i) a first interactor domain through the protein's N-terminal breakpoint; and
    - (ii) a second interactor domain through the protein's C-terminal breakpoint;and,
  - (b) optionally, additional amino acids that do not materially affect the basic and novel characteristic(s) of the claimed polypeptide,
- wherein the  $\beta$ -lactamase protein is functionally reconstituted only upon binding of the first and second interactor domain to a single ligand.

In the Office Action mailed September 26, 2005, the Examiner queries whether the phrase "polypeptide consisting essentially of" means "the polypeptide has a first interactor domain covalently bonded to N-terminal and C-terminal break point of circularly permuted  $\beta$ -lactamase protein." Office Action, page 3. Inasmuch as the Examiner is asking whether the first

interactor domain is covalently bonded to the circularly permuted  $\beta$ -lactamase protein through the N-terminal and C-terminal break points, one skilled in the art would immediately recognize that the answer is no. Claim 80 clearly states that the first interactor domain is covalently bonded to the circularly permuted  $\beta$ -lactamase protein through the protein's N-terminal breakpoint, and the second interactor domain is covalently bonded to the circularly permuted  $\beta$ -lactamase protein through the protein's C-terminal breakpoint.. See claim 80, stating "a first interactor domain covalently bonded to a circularly permuted  $\beta$ -lactamase protein through an N-terminal breakpoint of the circularly permuted  $\beta$ -lactamase protein...."

The Examiner further queries whether the phrase "polypeptide consisting essentially of" means "the claimed polypeptide has circularly permuted  $\beta$ -lactamase is [*sic*] linked to two interactor domain [*sic*] or the claim [*sic*] polypeptide has [*sic*] interactor domain and/or second interactor domain." Applicants submit that one skilled in the art would immediately recognize that the circularly permuted  $\beta$ -lactamase is linked to two interactor domains. Claim 80 clearly states that there is a first interactor domain **and** a second interactor domain. See claim 80, stating "a first interactor domain covalently bonded to a circularly permuted  $\beta$ -lactamase protein through an N-terminal breakpoint of the circularly permuted  $\beta$ -lactamase protein **and** a second interactor domain covalently bonded to the circularly permuted  $\beta$ -lactamase protein through a C-terminal breakpoint of the circularly permuted  $\beta$ -lactamase protein" (emphasis added).

Additionally, the Examiner queries whether the phrase "polypeptide consisting essentially of" means "the polypeptide may have different peptides or sequences linked or the polypeptide has first and/or second interactor domains." Inasmuch as the Examiner is asking whether the phrase "polypeptide consisting essentially of" means that the polypeptide may include additional amino acids that do **not** materially affect the basic and novel characteristic(s) of the claimed polypeptide, the answer is yes. See explanation *supra*. Applicants respectfully note, however, that the "[b]readth of a claim is not to be equated with indefiniteness." See MPEP §2173.04. Applicants further note that the Examiner has withdrawn the lack of written description rejection in response to Applicants' previous arguments. See Office Action, page 6.

The Examiner notes that "[g]enerally 'consisting essentially of' is use (*sic*) for a 'composition' and/or 'method' claims." Applicants respectfully point out, however, that Claim 80 is a **composition** of matter claim.

Finally, the Examiner suggests that the phrase "consisting essentially of" be replaced with "consisting of" or "comprising." It is noted that the originally filed claims included the "comprising" language and were rejected by the Examiner as allegedly failing to comport with the written rejection requirement. See Applicants' response dated October 5, 2004. Thus, while the Examiner's suggestion is appreciated, amending the claims to recite "comprising" would clearly not move prosecution forward.

And while the Examiner may feel the term "consisting of" may possess a greater degree of clarity, the use of this closed-ended term would allow competitors to easily design around the claimed polypeptide by making trivial changes, such as the addition of a single amino acid that does materially affect operability of the polypeptide. Moreover, where the claims provide a reasonable degree of clarity, the requirements of 35 U.S.C. §112, second paragraph are met, even where an examiner may feel alternative terms may possess a greater degree of clarity. See MPEP §2173.02. Applicants have fairly disclosed to the world the full breadth of their knowledge relating to this invention, and in exchange are entitled to a claim breadth that provides protection against competitors.

#### **D. Double Patenting**

Claims 80, and 84-88 stand provisionally rejected under the judicially created doctrine of double patenting as allegedly being obvious over claims 63-66 of co-pending U.S. Application No. 09/526,106. Applicants respectfully disagree.

Claims 63-66 of co-pending U.S. Application No. 09/526,106 do not teach or suggest a single polypeptide containing both a first and second interactor domain. Nor do claims 63-66 teach or suggest the use of a s circularly permuted  $\beta$ -lactamase. Rather, claims 63-66 set forth a polypeptide containing **only a first interactor domain** fused to a **fragment** of a  $\beta$ -lactamase protein. Therefore, because claims 63-66 of co-pending U.S. Application No.

Appl. No. 09/764,163  
Amdt. dated March 27, 2006  
Reply to Office Action of September 26, 2006

PATENT

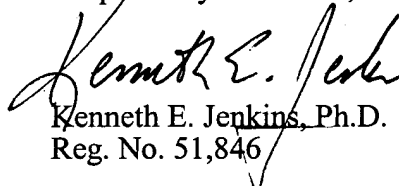
09/526,106 do not teach or suggest all the elements of the presently claimed invention, withdrawal of the rejection is respectfully requested.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,

  
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